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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/611,586 | 06/30/2003 | Mary T. Am Ende | PC9923B | 5236 |

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
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| EXAMINER | |
|---|---|
| JOYNES, ROBERT M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1615 | |

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/611,586 | AM ENDE ET AL. | |
| | Examiner | Art Unit | |
| | Robert M. Joynes | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-45 and 48-50* is/are pending in the application.

4a) Of the above claim(s) *46,47 and 51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-45 and 48-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *October 7, 2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Receipt is acknowledged of applicants' Information Disclosure Statement filed on October 7, 2003. Claims 46, 47 and 51 have been cancelled. Claims 1-45 and 48-50 are pending.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-45 and 48-50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S.

Patent No. 6,641,840. Although the conflicting claims are not identical, they are not patentably distinct from each other. U.S. Patent No. 6,641,840 claims a sustained release formulation for growth hormone secretagogues with very specific components and concentrations. The instant claims are broader in that they only claim a sustained release formulation for growth hormone secretagogues with a particular $C_{max}$ value without the specific components that achieve such a release profile. As such, the species, U.S. Patent No. 6,641,840 reciting the specific formulation, anticipates the genus, the instant claims reciting the generic sustained release composition.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7, 9-12, 14, 35, 36 and 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hipskind et al. (US 5773441) in combination with Carpino et al. (US 6107306).

Hipskind teaches various growth hormone secretagogues (hereinafter GHS) (Col. 9, line 25 – Col. 18, line 60). The GHS s of this invention can be administered by a variety of routes including oral, rectal, transdermal, subcutaneous, intravenous, intramuscular, and intranasal (Col. 44, line 4 – Col. 45, line 11). Oral compositions can be in the form of capsules, sachets, pills, powders, lozenges, elixirs, suspensions, emulsions, solutions, syrups, aerosols, ointments, and injectable solutions (Col. 44, lines 12-29). The compositions can also contained various known pharmaceutical excipients (Col. 44, lines 38-47). Further the compositions of the reference can be formulated so as to provide quick, sustained, or delayed release of the active agent after administration to the patient by employing procedures known in the art (Col 44, lines 47-50).

Hipskind does not expressly teach that the GHS is one of the particular GHSs recited in the instant claims.

Carpino teaches the specific GHSs recited in the instant claims (Col. 95-96, Claims 24 and 25). The reference further teaches that the GHSs can be formulated in various forms (Col. 31, line 20 – Col. 32, line 11). Carpino teaches that the selected dosage depends upon the desired therapeutic effect, on the route of administration and on the duration of treatment (Col. 32, lines 2-4).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare sustained release formulations of GHSs in various dosage forms. One of ordinary skill would choose the proper GHS for the desired treatment effect. One of ordinary skill would be able to prepare a sustained release

formulation that provides for the specific release profiles of the instant claims (See Claim 14). No criticality is seen in applicants' particular release profile.

One of ordinary skill in the art would have been motivated to do this to prepare dosage forms that provide maximum effectiveness for the particular treatment with the GHS and for the particular patient being treated.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 6-8, 13, 15, 41 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hipskind et al. (US 5773441) in combination with Carpino et al. (US 6107306) in further combination with Curatolo et al. (WO 9901122) or Curatolo (WO 9530422). The teachings of Hipskind and Carpino are discussed above. Neither Hipskind nor Carpino teach the various tablet formulations recited in the instant claims.

Both Curatolo references teach the various tablet formulation of the instant claims. Specifically, the references teach delayed release tablets (coated tablets), immediate release tablets and osmotic pump tablets ('122, Page 10, line 18 – Page 34, line 18; '422, Page 7, line 19 – Page 41, line 21). While these references do not teach the specific active agent, they are used to generally teach the different tablets formulations known in the art.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare sustained release formulations of GHSs in various tablet formulations. It is also within the skill on one in the art to prepare formulations that

have different release profiles as described in instant Claim 7. No criticality is seen in these particular release profiles.

One of ordinary skill in the art would have been motivated to do this to prepare different dosage forms that provide the desired sustained release effect for the particular GHS used, the particular intended treatment and the patient to which the formulation is administered.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 16-20, 22, 26-29, 31, 37, 38, 41-43 and 45 rejected under 35 U.S.C. 103(a) as being unpatentable over Hipskind et al. (US 5773441) in combination with Carpino et al. (US 6107306) in further combination with Devane et al. (US 6228398). The teachings of Hipskind and Carpino are discussed above. Neither Hipskind nor Carpino teach the combination of both an instant release portion and sustained release portion for the tablet formulations.

Devane teaches a multiparticulate modified release composition wherein the composition contains a first population of immediate release particles and a second population of sustained release particles (Col. 4, lines 10-44). Devane teaches that any active agent can be used in this particular modified release formulation, including hormones such as growth hormone release hormones (Col. 6, lines 13-63). The particles of this reference can be formed into tablets or filled in capsules (Col. 10, lines 15-35).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to formulate a dosage form that contains both an immediate release portion and a modified release portion. One of ordinary skill would choose the proper GHS for the desired treatment effect. One of ordinary skill would be able to prepare a sustained release formulation that provides for the specific release profiles of the instant claims (See Claim 14). No criticality is seen in applicants' particular release profile.

One of ordinary skill in the art would have been motivated to do this to provide a single dosage unit that performs both an immediate release function and a modified release function. It also provides a dosage unit for drugs in which patient tolerance is a problem. The dosage unit reduces or minimizes the development of patient tolerance to the active agents in the composition (Devane, Col. 4,lines 45-55).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 21, 23-25, 30, 32-34, 39, 40 and 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hipskind et al. (US 5773441) in combination with Carpino et al. (US 6107306) in further combination with Devane et al. (US 6228398) in further combination with Curatolo et al. (WO 9901122) or Curatolo (WO 9530422). The teachings of Hipskind, Carpino and Devane are discussed above. Neither Hipskind nor Carpino nor Devane teach the various tablet formulations recited in the instant claims.

Both Curatolo references teach the various tablet formulation of the instant claims. Specifically, the references teach delayed release tablets (coated tablets),

immediate release tablets and osmotic pump tablets ('122, Page 10, line 18 – Page 34, line 18; '422, Page 7, line 19 – Page 41, line 21). While these references do not teach the specific active agent, they are used to generally teach the different tablets formulations known in the art.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a dosage unit with both immediate and modified release formulations of GHSs in various tablet formulations. It is also within the skill on one in the art to prepare formulations that have different release profiles as described in instant Claim 37. No criticality is seen in these particular release profiles.

One of ordinary skill in the art would have been motivated to do this to prepare different dosage forms that provide the desired immediate and modified release effect for the particular GHS used, the particular intended treatment and the patient to which the formulation is administered. It also provides a dosage unit for drugs in which patient tolerance is a problem. The dosage unit reduces or minimizes the development of patient tolerance to the active agents in the composition (Devane, Col. 4,lines 45-55).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (571) 272-0597. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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